



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/286,818	04/06/1999	RONALD L. REAM	P99.0082	5472

29156 7590 12/17/2003

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 12/17/2003

43

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. Box 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 42

Application Number: 09/286,818
Filing Date: April 06, 1999
Appellant(s): REAM ET AL.

MAILED
DEC 17 2003
GROUP 2900

Robert M. Barrett
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/03/03.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-12 and 19-22 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

5,013,716	Cherukuri et al.	05-1991
5,922,347	Hausler et al.	07-1999

(10) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-11, and 19, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. US 5,013,716.

Cherukuri teaches chewing gum composition comprising elastomer as gum base, fats, oils, softener, filler, wax, colorant, plasticizer, acidulant, bulking agent, and sweetener (columns 8-10). The composition further comprises medicament (column 6). Cherukuri does not teach chewing the chewing gum, and continuing to chew the chewing gum to create a fluid pressure or saliva content of medicament of approximately 1700 to about 4400 ppm, causing the medicament to absorb through oral mucosa. However, chewing a chewing gum is obvious to one of ordinary skill in the art, and by continuously chewing the chewing gum, it would have been obvious to one of ordinary skill in this art that the medicament release into the saliva is either swallowed or absorbed through the oral mucosa. Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to chew or continue chewing the chewing gum to obtain the desirable amount of medicament to achieve a desired effect.

Art Unit: 1615

Claims 5, 12, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al.

Cherukuri is relied upon for the reason stated above. Cherukuri does not teach chewing the chewing gum at least twice a day. However, it is the position of the examiner that the amounts of medicament being administered are within the capability of the skilled artisan to determine a suitable dosage according to the daily needed basis.

Claims 1, 7, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al., and Hausler et al. US 5,922,347.

Cherukuri is relied upon for the reason stated above. Cherukuri does not teach chewing the chewing gum, and continuing to chew the chewing gum to force the medicament to absorb through oral mucosa.

Hausler teaches a stable chewing gum formulation comprises active drug (column 2, lines 8-56), filling, emulsifying, waxes, plasticising, and sugar (column 3, lines 11-67). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify Cherukuri's chewing gum composition with the teaching of Hausler to obtain a safe and stable chewing gum containing medicament, which is tolerated by the mucous membrane, because the references teach the advantageous results of medicament chewing gum compositions useful in pharmaceutical art.

Response to Arguments

Appellant's arguments filed 10/03/03 have been fully considered but they are not persuasive.

Appellant argues that Cherukuri does not disclose or remotely suggest a method of delivering a medicament which includes the step of chewing gum for at least two minutes. However, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to chew or continue chewing the chewing gum to obtain the desirability release of active agent/drug, because Cherukuri teaches a chewing gum composition suitable to deliver active agent/drug.

Appellant argues that Cherukuri does not teach a drug delivery system in the form of a chewing gum. Contrary to the applicant's argument, Cherukuri is well aware of the use of chewing gum composition as drug delivery system. Appellant's attention is directed to column 6, lines 13-15, where Cherukuri discloses "[I]n addition to the flavoring agents having a bitter or unpleasant off-note, set out above, the present invention also includes the combination of a medicament drug". Accordingly, Cherukuri does teach a drug delivery system in chewing gum products (see abstract).

Appellant argues that Cherukuri teaches the amount of medicament used in general is "the ordinary dosage required to obtain the desired result", and therefore, Cherukuri is clearly teaching away from the present invention where less than the ordinary amount is used. In response to applicant's argument, since applicant has not defined the "typical amount", the examiner cannot establish the patentability distinct between "less than a typical amount" and "ordinary amount" disclosed by Cherukuri.

Appellant argues that Cherukuri is completely silent as to any methods of chewing the chewing gum for at least two minutes to deliver a medicament. Although Cherukuri is silent as to the time of chewing the chewing gum, it is the position of the examiner that it would have been obvious for one of ordinary skill to continue chewing the chewing gum for at least 2 minutes, because Cherukuri teaches a chewing gum composition comprises medicament useful in pharmaceutical art. Therefore, it would have been obvious to the skilled artisan to keep chewing until the desired effect is obtained.

Appellant argues that the Patent Office has relied on hindsight reasoning in the use of Hausler, because Hausler does not teach any methods for delivering a medicament in a chewing gum composition that involves using less than the typical amount of medicament that is swallowed by an individual. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It is further noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined

Art Unit: 1615

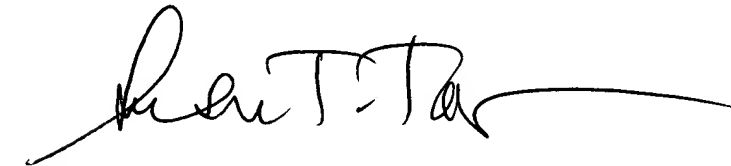
teachings of the references would have suggested to those of ordinary skill in the art.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Again, the examiner has not been able to compare "less than a typical amount" and "ordinary amount" taught by Cherukuri and Hausler. Thus, it is the position of the examiner that no patentability distinct can be seen in the particular limitation, because "less than a typical amount" can be any ordinary amount.

Appellant's argument of the 112, ¶12 is persuasive, and therefore, the rejection has been withdrawn.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,




S. Tran
December 3, 2003



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conferees

T. K. Page



REBECCA COOK
PRIMARY EXAMINER
GROUP 1200/614


~~James Spear~~

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135